

June 16, 2003

Steven J. Barbee, Ph.D.  
Director, Environmental Hygiene & Toxicology  
Arch Chemicals, Inc.  
501 Merritt 7  
P.O. Box 5204  
Norwalk, CT 06856

Dear Dr. Barbee:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 2-Chloropyridine posted on the ChemRTK HPV Challenge Program Web site on February 6, 2003. I commend Arch Chemicals, Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Arch Chemicals, Inc. advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at [tsca-hotline@epa.gov](mailto:tsca-hotline@epa.gov).

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director  
Risk Assessment Division

Enclosure

cc: W. Penberthy  
M. E. Weber

## **EPA Comments on Chemical RTK HPV Challenge Submission: 2-Chloropyridine**

### **Summary of EPA Comments**

The sponsor, Arch Chemicals, Inc., submitted the test plan and robust summaries to EPA on January 7, 2003 for 2-chloropyridine (CAS No. 109-09-1). EPA posted the submission on the ChemRTK HPV Challenge Web site on February 6, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The submitter needs to add measured melting point, vapor pressure and water solubility values found in standard sources to the submission. The submitter also needs to add a biodegradation study conducted according to OECD TG 301C that supports the other available data.
2. Health Effects. Adequate data are available for acute and genetic toxicity endpoints for the purposes of the HPV Challenge Program. EPA recommends a combined repeated-dose/ reproductive/developmental toxicity screening test rather than the proposed separate tests.
3. Ecological Effects. Only ECOSAR values for acute toxicity to fish, invertebrates and algae are provided. The submitter needs to provide adequate measured data for an analog in order to use predicted values for these endpoints.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

### **EPA Comments on the 2-Chloropyridine Challenge Submission**

#### **Test Plan**

##### Physicochemical properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

Adequate data are available for the purposes of the HPV Challenge Program. The submitter needs to add data available from standard sources to the submission. Estimated values are usually not acceptable for most of these endpoints.

*Melting Point.* Standard sources show measured values (-46 to -46.5°C) confirming that the melting point is below 0°C. The submitter should consider adding the measured values to the robust summary.

*Vapor Pressure.* The submitter provided an estimated value of 1.56 mm Hg at 25°C. However, according to OECD TG 104, estimated values are acceptable only if they are less than  $7.5 \times 10^{-8}$  mmHg at 25°C. Standard sources show numerous measured values including 2.18 mm Hg at 25°C (see, for example, Beilstein Online database, 2003, reference number 5-20-05-00402). These references need to be added to the robust summaries.

*Water Solubility.* The submitter reports a value of 2,000 mg/L, which EPA was unable to verify. Standard sources show values of 10,000 and higher. EPA recommends that the submitter substitute or add the higher measured values to the robust summary.

##### Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

Adequate data are available for the purposes of the HPV Challenge Program. EPA agrees with the proposed technical discussion for stability in water.

*Biodegradation.* The submitter provided data from multiple biodegradation studies, all of which were conducted according to non-OECD guidelines. EPA identified an OECD TG 301C study (Chemicals Inspection and Testing Institute, 1992). This study should be added to further support the conclusion that 2-chloropyridine is not readily biodegradable.

#### Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data are available for acute toxicity and genetic toxicity for the purposes of the HPV Challenge Program.

EPA agrees that testing is needed for the repeated-dose, reproductive, and developmental toxicity endpoints. However, EPA recommends that the submitter conduct a combined repeated-dose/reproductive/developmental toxicity screening test (OECD TG 422) rather than the proposed separate tests (OECD TGs 407 and 421). The submitter needs to specify the route of administration of the test substance for this testing.

#### Ecological Effects (fish, invertebrates, and algae)

The submitted fish, invertebrate, and algal predicted values using ECOSAR are acceptable only with the support of measured data on an appropriate analog. Otherwise, the submitter needs to test this chemical for all acute ecotoxicity endpoints.

### **Specific Comments on the Robust Summaries**

#### Environmental Fate

*Fugacity.* The submitter needs to provide the input parameter values.

#### Health Effects

The submitter needs to provide information on the purity of the test substance, if available, for several of the studies.

#### Ecological Effects

The submitter needs to provide the input values for the ECOSAR predictions.

### **Followup Activity**

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

### **References**

Chemicals Inspection and Testing Institute; Biodegradation and Bioaccumulation data of Existing Chemicals Based on the CSCL Japan; Japan Chemical Industry Ecology – Toxicology and Information Center, ISBN 4-89074-101-1. 1992.